

Guidance for Industry and/or FDA Reviewers/Staff

Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses

Draft Guidance – Not for Implementation

**This guidance document is being distributed for comment purposes only.
Draft released for comment on October 5, 1999**

This document supersedes Draft Guidance for Preparation of FDA Submissions of Silicone Gel-Filled Breast Prostheses - 5/11/92; Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses - 1/18/95; and Draft Guidance for Testing of Alternative Breast Prostheses (non-silicone gel-filled) - 9/1/94

This document was replaced on 8/13/01 by the document located at:

<http://www.fda.gov/cdrh/ode/guidance/1354.html>